Remarks

Claims 1-4, 7-30, 33-35, and 54-63 are pending upon entry of the foregoing amendments.

Information Disclosure Statement

Applicants filed a Supplemental Information Disclosure Statement on April 4, 2007. It apparently crossed in the mail with the Office Action mailed later on April 10, 2007. Applicants respectfully request consideration of the IDS and return of the initialed Form PTO/SB/08a.

Amendments to the Claims

Claim 7 has been amended to correct the claim dependency.

Claim 55 has been amended into independent form and amended for internal clarity and consistency, and new claims 60-63 have been added. Support for these amendments can be found in the specification, for example at page 22, lines 10-19 and page 24, lines 5-12. No new matter has been added.

Rejection Under 35 U.S.C. § 112

Claims 7 and 8 were rejected under 35 U.S.C. § 112, second paragraph, as indefinite. The rejection is respectfully traversed. Claim 7 is currently amended to correct the claim dependency, thereby providing sufficient antecedent basis for each limitation in claims 7 and 8.

Rejection Under 35 U.S.C. § 102

Claims 1-4, 7-14, 16-30, and 33-34 were rejected under 35 U.S.C. § 102(a) and § 102(e) as anticipated by U.S. Patent Publication 2002/0072784 by Sheppard Jr. et al. (hereinafter "Sheppard"). The rejection is respectfully traversed.

One skilled in the art understands that Sheppard does not disclose a means for rupturing a reservoir cap by *electrothermal ablation*. The term "electrothermal ablation" is clearly defined in the specification as amended November 8, 2006. Electrothermal ablation is a mechanism for rupturing a reservoir cap requiring that electric current flow *directly through the reservoir cap.* Electric current provides *local heating* of the reservoir cap in an amount effective to rupture the reservoir cap. The reservoir cap itself functions as a heat generator. Electrothermal ablation does not depend on a separate resistor or resistive heater element. As evidenced by the specification and the Rule 132 Declaration of Dr. Santini, "when an effective amount of an electrical current is applied through the leads and reservoir cap, the temperature of the reservoir cap is locally increased due to resistive heating, and the heat generated within the reservoir cap increases the temperature sufficiently to cause the reservoir cap to be electrothermally ablated (i.e., ruptured)." The mechanism is analogous to the failure of a conventional electrical fuse.

Sheppard does not teach or suggest electrothermal ablation. Instead, as evidenced by the Rule 132 Declaration of Dr. Santini, Sheppard discloses an electrochemical mechanism and a thermal mechanism. These mechanisms utilize reservoir caps formed of an electrically-responsive polymer and a thermally-responsive polymer, respectively.

The integrity or porosity of reservoir caps formed of an electrically-responsive polymer is modulated by an *electrochemical* mechanism. The electrochemical mechanism is not an electrothermal mechanism. Instead, an electric potential is applied between an anodic reservoir cap and a separate cathode to cause the reservoir cap to oxidize and dissolve into a surrounding conductive fluid. (See Rule 132 Declaration of Dr. Santini). Unlike electrothermal ablation, the electrochemical mechanism requires does not rupture by heat generation within the reservoir cap.

The integrity or porosity of reservoir caps formed of a thermally-responsive polymer is modulated by a thermal mechanism. The thermal mechanism requires that electrical energy be applied to a resistor "nearby," but distinct from, the reservoir cap, to heat and rupture or disintegrate the reservoir cap. (See Rule 132 Declaration of Dr. Santini). Unlike electrothermal ablation in which the *reservoir cap itself* functions as a heat generator, the thermal mechanism requires a resistor or resistive heating element that is separate and distinct from the reservoir cap.

Sheppard simply does not disclose a means for opening reservoirs by an electrothermal ablation mechanism as that term is defined in the specification and understood in the art. Furthermore, the Examiner has provided no evidence to rebut Applicant's factual evidence that Sheppard fails to teach "any type of reservoir cap disintegration mechanism that involves electrothermal ablation." ¶4, Rule 132 Declaration of Dr. Santini. The rejection is improper and must be withdrawn.

Rejections Under 35 U.S.C. § 103

Claims 15 and 54 were rejected under 35 U.S.C. § 103(a) as obvious over Sheppard in view of U.S. Patent 6,112,116 to Fischell et al (hereinafter "Fischell"). Claim 35 was rejected under 35 U.S.C. § 103(a) as obvious over Sheppard in view of U.S. Patent 6,726,920 to Theeuwes et al. (hereinafter "Theeuwes"). Claims 55-59 were rejected under 35 U.S.C. 103(a) as obvious over Sheppard. Claims 55-59 also were rejected under 35 U.S.C. § 103(a) as obvious over Sheppard in view of U.S. Patent Application Publication No. 2004/0082937 by Ausiello et al (hereinafter "Ausiello"). The rejections are respectfully traversed.

Sheppard and Fischell, Sheppard and Theeuwes

As explained above, Sheppard fails to disclose or suggest devices that include means for disintegration of reservoir caps by electrothermal ablation. Neither Fischell nor Theeuwes supplement this deficiency.

Fischell discloses a myocardial infarction treatment system that includes a medication release device having a case and medication reservoirs formed within the case by thin-walled metal bellows. The chamber in the case contains a pressurized inert gas which causes the medications to be quickly released when an outlet valve is opened. This Fischell mechanism clearly is not similar to or suggestive of *electrothermal ablation*. Furthermore, *opening a valve* to cause release teaches away from *disintegrating a reservoir cap* to initiate release.

Theeuwes discloses devices and methods for delivery of a drug directly to the surface of an organ such that the drug traverses the organ surface and enters the organ tissue. Nothing in Theeuwes teaches *electrothermal ablation* of a reservoir cap.

Sheppard

As explained above, Sheppard fails to disclose or suggest devices that include means for disintegration of reservoir caps by electrothermal ablation. Furthermore, Sheppard fails to disclose or suggest connecting a pair of electrical leads—input and output leads—connected to a single reservoir cap.

The Examiner contends that it would have been obvious to modify the wireless system as taught by Sheppard with leads since it was known in the art to employ leads or leadless transmission of data to medical devices. However, the transmission of data to/from a medical device is not analogous to providing conducting leads to and from a reservoir cap and delivering electrical current to the reservoir cap effective to disintegrate the reservoir cap by electrothermal ablation. The electrical leads have entirely different purposes.

Furthermore, as disclosed in the specification, electrical input and output leads should be designed to operate with the reservoir cap to cause electrothermal ablation. (See, e.g., page 21, line 30 to page 22, line 19). Design of conducting leads to and from the reservoir cap would not have been obvious to one having ordinary skill in the art at the time the invention was made.

Sheppard and Ausiello

Ausiello was disqualified as a reference under § 103(c) in Applicants' submission filed September 21, 2006. Examiner recognized the disqualification in the Advisory Action mailed on October 25, 2006. Any rejection over Ausiello thus must be withdrawn.

Conclusions

Applicants respectfully submit that the claims are patentable over the prior art of record. Prompt allowance of each of claims 1-4, 7-30, 33-35, and 54-63 is therefore respectfully solicited.

The undersigned kindly invites the Examiner to contact him by telephone (404.853.8068) if any outstanding issues can be resolved by conference or examiner's amendment.

Respectfully submitted,

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